

REMARKSStatus of the claims

Claims 1-2, and 4-20 are pending in the present application. Claims 12 and 13 have been withdrawn from consideration. Claims 1, 4, 7-9 and 15-20 have been amended herein to place the claims in better format for examination. Claim 3 has been cancelled. No new matter has been added with the amendments to the claims. As such, entry and consideration thereof are respectfully requested.

Substitute specification

Upon review of the specification, Applicants noted numerous typographical, grammatical and translational errors. As such, a substitute specification has been submitted herewith, which corrects these errors. No new matter has been added to the substitute specification.

Rejections under 35 U.S.C. §102

Claims 1-3 have been rejected under 35 U.S.C. §102(b) as being anticipated by USP 6,190,691 (the '691 patent). The Examiner asserts that the '691 patent teaches a topical composition having multiple gelling agents, papain, preservatives, anesthetics, antimicrobial agents, analgesics and emulsifiers. The Examiner relies on the section "(1)Topical Formulations" beginning in column 43 for teaching all of the elements of claims 1-3, except for papain, which the Examiner finds in column 51, line 41, under the section entitled "(7) Iontophoresis".

Applicants traverse this rejection and withdrawal thereof is respectfully requested. The present invention, as most broadly encompassed in amended claim 1, is drawn to,

a topical composition in form of a gel for treating skin burns comprising:

a first barrier gel for skin protection comprising carboxypolyethylene (carbopol) as a first thickening agent and an emulsifier agent in an aqueous carrier;

a second barrier gel for skin protection comprising a second thickening agent and a preservative agent, in an aqueous carrier;

an active principle having proteolytic activity; and

an anesthetic agent.

Thus, the present invention is drawn to a topical composition that contains four separate components, which each have a separate and specific function in treating burns. The '691 patent pertains to methods of screening for agents that suppress cytokine production and methods of using such agents therapeutically.

The '691 patent pertains to methods of inhibiting cytokine production, i.e. proteins having immunocompetent activity. The '691 patent further discloses the use of substances such as loperamide and diphenoxylate for targeting the immunological inhibition of TNF (Tumor Necrosis Factor). The reference in the '691 patent that is made to the components of the gels in connection with topical products relates only to conventional pharmaceutical agents, dilutants and carriers commonly used, that is: it is descriptive and illustrative information of the preparation of a product and is not limited to a specific pharmacological function, which was the case with the present invention and which therefore dictated a specific composition with the present invention. The mere mention of the elements available for manufacturing gels and their pharmaceuticals features does not undermine the novelty in the use of properties of the carbopol and CMS substances, whose pharmacological applicability is described in the present application, in combination with the inherent therapeutic effects over superficial skin lesions of the papain and associated adjuvants. Further the reference to "Iontophoresis" in the '691 patent refers to the use of electrical fields to administer the therapeutic agent of the TNF inhibitor. When addressing the electric stimulation of the skin, the authors cite a number of substances that may perturb the normal structure of the skin, among them papain, and thus iontophoresis is completely unrelated to the instant invention.

Applicants note that there are some very passing reference to burns in the '691 patent (see e.g. column 10, line 50 and column 12, lines 41-47). However, the reference to burns is strictly with respect to the involvement of TNF production in burns. There is no disclosure or suggestion of the composition of the invention in the '691 patent. The Examiner asserts that column 44, line 5 teaches that "multiple thickeners may be used in the topical formulation". However, column 44, line 5 does not teach the use of multiple thickeners in a single formulation. Rather the patent simply discloses a generic list of possible thickening agents. In addition, the

Examiner's reliance on the disclosure of papain appears to be misplaced. Papain is disclosed in a laundry list of well over 100 different examples of agents, which are "stratum corneum lipid perturbants". From a review of the list it is seen that few of the agents listed are proteolytic. Finally, the Examiner points to column 69, line 56 as disclosing proteolytic cleavage. However, this portion of the '691 patent discusses the detection of TNF that was isolated from lamellar bodies. Thus, the Examiner improperly combined different and irrelevant portions of the reference to achieve elements of the invention. The '691 patent fails to disclose the specific combination of elements as recited in claim 1. As such, the invention of claim 1 and dependent claim 2 is not anticipated by the disclosure of the '691 patent and withdrawal of the rejection is respectfully requested.

**Rejections under 35 U.S.C. §103**

Claims 1-11 and 14-20 have been further rejected as being obvious over the '691 patent, either alone or in combination with the indicated secondary references. The secondary references are cited for the teachings of the general properties of the additional components listed in the dependent claims. For example, USP 5,446,070 is relied on for the general teaching of the use of lidocaine as a topical anesthetic.

All of the rejections are based on the erroneous interpretation of the '691 patent discussed above. As such, the invention of claims 1-2, 4-11 and 14-20 is similarly not obvious over the '691 patent combined with the indicated secondary references. Withdrawal of the rejections is therefore respectfully requested.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact MaryAnne Armstrong, PhD, Registration No 40,069 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

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Respectfully submitted,

By   
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Attachment: Substitute specification (marked-up copy and clean copy)